

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P., and
JANSSEN SCIENCES IRELAND
UNLIMITED COMPANY,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC,
AMNEAL PHARMACEUTICALS
COMPANY GMBH, AMNEAL
PHARMACEUTICALS OF NEW YORK,
LLC, and AMNEAL PHARMACEUTICALS
PVT. LTD.

Defendants.

Civil Action No. 2:18-cv-17585-WHW-CLW

Hon. William H. Walls

Hon. Cathy L. Waldor

CONSENT JUDGMENT AND ORDER

This action for patent infringement having been brought by Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, “Janssen”) against Defendants Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Pvt Ltd. (collectively, “Amneal”) for infringement of United States Patent Nos. 8,518,987, 7,126,015, and 7,595,408 (collectively, “Janssen Patents”);

Amneal and Plaintiffs have entered into a Settlement Agreement to settle this action (the “Settlement Agreement”) and a License Agreement (the “License Agreement”) under which Janssen has granted Amneal a license to the Janssen Patents, as defined below (the “License”), pursuant to the terms and conditions in the Settlement Agreement and License Agreement;

Janssen currently markets in the United States pursuant to New Drug Application No. 21-976 tablets containing darunavir ethanolate for the treatment of HIV-1 infection, all strengths of which Janssen currently sells under the trade name PREZISTA® (the “Prezista Product”);

Amneal Pharmaceuticals Company GmbH filed or caused to be filed Abbreviated New Drug Application (“ANDA”) No. 212493 (“Amneal’s ANDA”) containing a “paragraph IV certification” with respect to United States Patent No. 8,518,987 and seeking FDA approval to make, sell, offer for sale, use and/or import in or for the United States a product under or described in Amneal’s ANDA (the “Amneal Product”);

For the purposes of this litigation, Amneal acknowledges that at least one claim in each of the Janssen Patents is valid and enforceable solely with respect to the Amneal Product in the United States;

The Parties have agreed to terminate the pending litigation by the entry of this Judgment and Order; and

Plaintiffs and Amneal now consent to this Judgment and Order.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.
2. Amneal admits, for the purposes of resolving this litigation, that at least one claim in each of the Janssen Patents are valid and enforceable solely with respect to the manufacture, use, sale, offer for sale, and importation of Amneal Product in the United States.
3. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Plaintiffs against Amneal and its affiliates, or by Amneal and its affiliates

against Plaintiffs, in this action solely with respect to the Amneal Product and the Janssen Patents are hereby dismissed with prejudice.

4. Amneal admits that absent a license from Plaintiffs, the manufacture, sale, offer for sale, use or import of the Amneal Product in the United States would constitute infringement of the Janssen Patents.

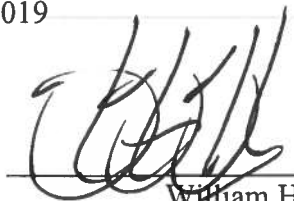
5. Amneal and its affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States the Amneal Product during the life of the Janssen Patents until the occurrence of the Start Date under the License Agreement, or as otherwise permitted under the License Agreement.

6. The parties waive all right to appeal from this Judgment and Order.

7. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment and Order.

8. Each party is to bear its own costs and attorneys' fees.

IT IS SO ORDERED this 1 day of May 2019



William H. Walls
United States District Judge

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